### PUBLIC MEETING

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International Trade Center
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## COMMISSIONERS PRESENT:

GLENN M. HACKBARTH, Chair ROBERT D. REISCHAUER, Ph.D., Vice Chair SHEILA P. BURKE AUTRY O.V. "PETE" DeBUSK NANCY-ANN DePARLE DAVID F. DURENBERGER ALLEN FEEZOR RALPH W. MULLER ALAN R. NELSON, M.D. JOSEPH P. NEWHOUSE, Ph.D. CAROL RAPHAEL ALICE ROSENBLATT JOHN W. ROWE, M.D. DAVID A. SMITH RAY A. STOWERS, D.O. MARY K. WAKEFIELD, Ph.D. NICHOLAS J. WOLTER, M.D.

### AGENDA ITEM:

# Dialysis services: assessing payment adequacy and updating payments -- Nancy Ray

MS. RAY: Good morning.

Recall last month we discussed two aspects of outpatient dialysis payment policies. First, we discussed assessing payment adequacy and updating the composite rate for 2005. We do this annually so that Medicare's payments can cover efficient providers' costs and in doing so maintain beneficiaries' access to care.

The second issue we discussed last month concerned linking payments to quality, and in doing so improving the quality of outpatient dialysis care.

Currently Medicare has no mechanism to directly reward providers and here we're talking about dialysis facilities and the physicians who treat dialysis patients who improve quality. Recall that in our June 2003 report the Commission endorsed using quality incentives.

So let's move on to our assessment of payment adequacy. Our framework examines six factors to assess payment adequacy and the first is beneficiaries' access. Here we've concluded that beneficiaries don't appear to be facing systematic barriers in accessing care. We did an analysis of the pattern of facility closures, and this suggests that beneficiaries should not be having problems accessing care in rural areas, HPSAs. In addition, the percentage of the population that is minority and that the percentage of the households receiving public assistance income does not appear to be correlated with facility closures. Rather, facility closures seem to be associated with facilities that are small, hospital-based, and non-profit.

A second factor we consider in our payment adequacy framework is the volume of services. And here we've looked at the volume of services in terms of Medicare payments because we don't have a common unit. And let me just spend a little bit of time talking about each of these bars.

The first bar shows the average annual growth in payments for composite rate services between 1996 and

2001. These have been growing by about 6 percent. The growth is primarily being driven by the growth in the beneficiary population, which is also roughly at about 6 percent.

The next bar shows a 12 percent average annual growth in payments for erythropoietin. This bar, the increase is being driven both by the increase in the patient population as well as by the increasing dose of erythropoietin between 1996 and 2001. Recall that erythropoietin, the payment rate is set by Congress and that payment rate was not changed between 1996 and 2001.

The third bar is the rate of growth for other injectable drugs. This includes vitamin D analogs, injectable iron, injectable antibiotics. Between 1996 and 2001 the average annual growth in payments for these drugs was about 25 percent. The growth in these services is being driven by a combination of the growth in the patient population, the increasing acquisition cost because there has been some substitution from older drugs to more new costly drugs.

Your mailing materials also note that there is some variation in the use of these drugs by provider type.

So here we can conclude that the volume of services is growing, is keeping up with the number of patients.

A third factor we look at in our framework is quality of care. Here we've concluded that quality is improving for some measures. CMS's data shows substantial improvements in dialysis adequacy and anemia between 1993 and 2001. However, CMS's data also show that other measures are flat, specifically nutritional measures and vascular access care. I think this demonstrates the need for continued efforts to improve quality and to address these continued concerns about dialysis quality. Later on in the presentation we will discuss the use of quality incentives as a means to improve quality.

This slide shows the proportion of for-profit facilities is growing. We show this as an indirect measure this time of access to capital, which appears to be sufficient. Last month you had asked about the growth in the for-profit chains and where this growth

was coming from. So we compiled information from their SEC filings and annual reports and that showed that in 2002 the four major national chains, they opened 104 facilities and acquired 35 facilities in 2002. So between the openings in 2001 and -- I'm sorry, total number in 2001 and total number in 2002, there was about roughly a 5 percent growth in the number of facilities operated by the four major chains.

Just to give you a frame of reference, in 2002 there was a total of about 4000 dialysis facilities and about two-thirds were operated by these four national chains.

Let's move on now to the Medicare margin. Here we have calculated it for 2001. We used 2001 cost report data because of the low proportion of facilities that are in the file available from CMS for 2002.

So here we see that the Medicare margin is 5.2 percent for all facilities, 5.4 percent for urban facilities and 4.3 percent for rural. These 2001 date are adjusted by an audit factor. 1996 is the most recent year that cost reports were audited. Our analysis indicates that audited costs are 96 percent of reported costs. Recall that ProPAC included an audit factor in their update analyses and an older audit found that audited costs were 88 percent of reported costs.

I do want to mention here that data presented by the major chains, they have used their 2002 data and they have calculated a 2002 margin of basically zero, roughly zero. We have a couple of concerns with this. First, it does not include the audit factor. And second, we have issues with how they have cleaned the data.

So now let's move on to our estimated Medicare margin for 2004. We start our estimation process by beginning with our 2001 payments and current law does not update the composite rate for 2002, 2003 or 2004. So projecting out our 2001 data to 2004, it yields a margin of 2.7 percent. This includes a conservative assumption about the increasing proportion of payments for injectable drugs relative to composite rate services. If you remove that conservative assumption, the margin would be lowered by .6 of a percent. So it would be lowered to 2.1 percent.

So to summarize, our analysis of market factors suggest that beneficiaries are not -- go ahead MR. HACKBARTH: I was thinking about what you just said and I just want to make sure I understand the nature of the conservative assumption.

MS. RAY: Here's what we did. If you recall in your mailing materials, we showed that the proportion of payments for injectable drugs relative to composite rate services has increased from 1996 it was 30 percent. In 2001 it was 40 percent. But I only used the most recent three-year trend from 1999 to 2001. And there it's actually -- it's a 37 percent to 41 percent increase. So the 2.7 percent number would have been higher if I used the '96 to '01 trend for the longer time period because the share has increased more for that time frame than the most recent couple of years.

DR. ROWE: [off microphone.] So what do you think the Medicare margin actually is?

MS. RAY: The Medicare margin is 2.7 percent if we -- when we project out from 2001 to 2004, if we increase the share of injectable payments relative to composite rate payments from 41 percent to about 43 percent.

 $\ensuremath{\mathsf{MR}}\xspace$  . HACKBARTH: And if we assume that there's no growth.

MS. RAY: Then it would be 2.1 percent. I'm sorry if I wasn't clear the first time.

DR. ROWE: So it's 2.1 to 2.7 percent.

MR. HACKBARTH: 2.1 if the relationship between injectables and dialysis stayed the same as it was in 2001.

MS. RAY: Yes.

MR. HACKBARTH: 2.7 if injectables d continued to grow relative to the composite payment.

MS. RAY: Yes.

So to summarize our market factors, again no systematic problems in accessing care for beneficiaries. I showed you at the last meeting that providers seem to have sufficient capacity to treat patients. The number of in-center hemodialysis stations is keeping up with patients. There is a growing volume of services, as indicated by the payment data. We see improving quality on some measures. And there appears to be sufficient

access to capital.

So moving to the second part of our update framework, how should Medicare change payments in calendar year 2005? There are two important factors to consider here. The first, our framework reflects our policy goal that in the aggregate providers should be able to improve their efficiency while maintaining service quality.

The second is the change in input prices between 2004 and 2005. Past years we've solely relied on the Commission's market basket to estimate the costs in the next payment year. And so the Commission's market basket estimates costs will rise by 2.3 percent between 2004 and 2005. CMS just released their dialysis market basket, they released it this year. This market basket estimates costs will rise by 3 percent between 2004 and 2005.

Our likely direction is to move to the CMS market basket in the future. However, we have a few technical issues that we raised in our October report on modernizing the dialysis payment system and we would like to work with the Agency on these issues. The two important issues are the weighting of the cost categories and the change in the distribution of services when audited data are used.

So using these two market baskets and including our policy goal for productivity, we estimate that efficient providers' costs will rise by 1.4 to 2.1 percent between 2004 and 2005. That tenth of a percent difference is because of the new dialysis market basket that CMS just released.

Let's just briefly discuss the two important payment changes by DIMA in 2005. DIMA increases the composite rate by 1.6 percent. DIMA also makes another important change to the outpatient dialysis payment system. It case-mix adjusts the payment for composite rate services and the difference between payments for and the cost of injectable drugs. That is the spread on the injectable drugs. It also pays the acquisition costs for injectable drugs.

Just to let you know, to keep this in mind, that CBO scored this latter provision, the case-mix adjustment and the paying based on the acquisition

costs, as budget neutral.

So this led us to our draft recommendation that Congress should maintain current law and update the composite rate by 1.6 percent for calendar year 2005. This would have no spending implications relative to current law.

DR. ROWE: Thank you, Nancy.

I need some help and here's my concern. Somewhere along this logic train I'm making a serious mistake but Medicare is the major source of revenue for many of these facilities. And thus, the Medicare margin is probably a reasonable proxy for the overall margin unless commercial payers such as myself are paying something that's much, much higher and represents a much larger portion of the population, and I think we do. But you can tell us what the overall margins are.

You're talking about overall margins depending on this one issue we're talking about. Pre-tax, I'm assuming, this is pre-tax of 2.1 to 2.7 percent, and CMS says the costs are going to increase 3 percent. We differ a little bit with their analysis and we think the costs may increase somewhere between 1.4 and 2.1 percent and we're going to increase by 1.6 percent. We're going to drive these people out of -- I don't understand how they can have access to capital at that rate. I don't understand how their stock prices are doing so well. I don't understand why more people are entering the market. There's something wrong here. What am I missing? Where are they making the money?

DR. NEWHOUSE: [off microphone.] Epo.

DR. ROWE: But epo is paid by Medicare.

MR. HACKBARTH: The margin is calculated including the drugs.

DR. ROWE: No. The Medicare margin was 2.1 to 2.7 inclusive, everything that Medicare pays for. So that's not the answer. What is the answer?

DR. MILLER: Let me ask one thing to clarify. The margins that we reported, the 2.7, includes the drugs and the composite rate?

MS. RAY: Yes.

DR. MILLER: So that's the first clarification. And then the second point is this update, the 1.6, applies to the composite rate?

MS. RAY: Yes.

DR. ROWE: So is there any increase in the

drugs?

MS. RAY: Drugs will continue to be paid as they occur --

DR. ROWE: But this DIMA thing is budget neutral.

MS. RAY: That's right. For 2005, that's right.

DR. ROWE: So why wouldn't a prudent investor buy a share of these -- I mean, I must be missing some huge thing here.

MR. SMITH: [off microphone.] Budget neutral, Jack, doesn't mean less money. It means less money relative to current law. It will be more money --

DR. ROWE: I understand, but is there enough there to make this a -- are these pre-tax margins, first of all?

MS. RAY: The margins represent Medicare payments to allowable costs.

DR. ROWE: So if we take a number like 2.5, so that's 1.5 after tax. That's inconsistent with the access to capital, the stock performance, the increase in the -- isn't it?

MR. HACKBARTH: I think, in part, Jack, this is why we look at factors other than just the margin. All of the other indicators, including the rapid growth of the for-profit piece of the industry, suggest to me that the payments are adequate.

DR. ROWE: I understand. I agree. Are the returns on capital -- do you know what the returns on capital are?

DR. REISCHAUER: You don't look at the margin on revenues to determine the profitability of a company. I mean, supermarkets operate at less than 1 percent. It's the invested capital.

DR. ROWE: I understand. I just asked what the return on capital was.

MS. RAY: I'd have to get back to you on that.

DR. ROWE: I'm not trying to make a case for or against. I'm just trying to connect all these dots and I'm asking what I'm missing. And maybe the returns on capital are 35 percent, for all I know. But I would

think this is a pretty capital intensive business and, in fact, they're not that high. But I don't know.

It's a puzzlement, but thank you for telling me how you measure the profitability of a company. I appreciate it.

DR. REISCHAUER: You asked what you were missing and you beat up Nancy left and right. And then, at the end, you try and slip in something so we don't --

DR. ROWE: That's why I thanked you but I slipped it in before you mentioned it.

MR. HACKBARTH: Usually, it takes us a while to get to this point, and here we are the first presentation. Sheila?

MS. BURKE: Nancy, good job. I have a couple of questions on the chapter and how we describe what's going on as compared to Jack's issue around the recommendations.

Twofold. One, there is a discussion in the chapter about two-thirds of free-standing facilities that were opened and your comment about the continued opening of free-standing, and the comment made that the openings suggest that there is adequate profitability and access to capital.

What is not discussed in the chapter at all is, in fact, the implications of the absolute decline in non-profits, the continued decline and the continued increase in for-profits and what, in fact, is occurring with respect to the non-profits. There is an observation that's specific to the adequacy related to for-profits. There is nothing about why, in fact, we continue to see a decline in non-profits in our discussion. And so that's just an area that we may want to give some attention to.

The second issue is really my trying to understand, although this is a relatively small percentage of the population, and that is what is occurring with those patients who have chosen to do inhome as compared to in-center dialysis?

In the conversation you talk a bit about the inequity of the treatment of drug costs for the home-based patient who only has epo taken care of, but none of the other drug costs. And of course, the new legislation will potentially exacerbated -- well, it

certainly won't do anything to address has issue with respect to the in-home patient.

I wondered whether there was attention that needed to be given to that patient, what was happened with respect to the equity issues with the in-home patient, whether the policies in fact continue to encourage people to go in-center, and if there is a reason to do that for purposes of quality. Because the other issue that is not specifically pointed out is you note that there has been some progress in the context of some measures but less so in others. What I don't know is whether there is a difference between the measures quality and the impact on the in-center patient and the at-home patient, whether we see dramatic differences, whether it is in nutrition issues, presence of anemia, issues in terms of the site treatment.

It would be helpful to understand do we want a policy that, in fact, encourages people to go in-center as compared to stay at home? And has there been a radical difference, or is there a real difference in the quality indicators between those two sets of patients? And if there is, then it would seem to me that should relate to some kind of a policy over the long term in terms of reimbursement and what it is we want to encourage or discourage.

Again, it's a relative small percentage of the population but it is still a continuing population that has chosen peritoneal and chosen to stay home.

MS. RAY: Right. Just two points to add on, and we will definitely augment the chapter with the quality information and address those points. Just two points right now, however.

Remember that the composite rate as its constructed right now actually gives an incentive for peritoneal dialysis. And despite that incentive, and I included this in your mailing materials, the proportion of peritoneal patients has declined roughly by about 10 percent in the last decade.

MR. FEEZOR: [off microphone.] Incentive to whom?

MS. RAY: If you just looked at the composite rate payment to the provider because peritoneal costs are, on average, lower than the in-center because you

don't have the capital costs.

DR. REISCHAUER: Nancy, on page 16 you referred to the fact that some of these chains have their own laboratories and it wasn't clear whether you were saying they make excess profits in the laboratory business and those aren't reflected in these margins, that they overuse laboratory service because of this. I think if we're going to put something like this in, we have to say why we're doing it and whether it's really relevant whether that's within the same corporate entity versus there's some independent laboratory somewhere that's making a bundle on this. It sort of made me a little uncomfortable the way we had it in the text.

MS. RAY: I was not in any way meaning to suggest that there's any overuse of laboratory services. Rather, there are certain laboratory tests that are paid for outside of the composite rate if they go above a certain amount per month and so forth. So those are sent out to the laboratory and Medicare pays the laboratory. It just so happens that the national chains own their own laboratories.

So the payments and costs associated with those services that are associated with the dialysis treatment are not included in our payment margin.

DR. REISCHAUER: I understand that, but we don't want to have a payment that's adequate only if you run a laboratory on the side. What you're basically saying is so these guys might not go out of visit because they're selling cars or doing something else on the side. But that's really not relevant to what the payment level should be for dialysis treatment.

MS. RAY: I was not suggesting that, but in keeping with our recommendation of broadening the bundle and including all services to the extent possible associated with the dialysis treatment, just like our margins have included the use of injectable drugs in a perfect world, we have included separately billable drugs, we would want to include these separately billable lab tests because they are associated with the dialysis treatment. And we can't because it would be --well, we not yet because it's a very tough claims level analysis to do that.

But the fact remains that I think ultimately

we would want to include these in the broader bundle. And that's why I mentioned them when we're thinking about payment adequacy.

DR. REISCHAUER: [off microphone.] I agree with that but there's sort of an innuendo here.

MS. RAY: I hear you. We'll address that.

MR. FEEZOR: Nancy, three questions. Sheila touched on one about the quality of home versus institutional. But in your access, was there any significant difference between CON and non-CON states, that you could determine? Or was that discernable?

MS. RAY: I did not do it that way. For the next cycle we could take a look at that.

MR. FEEZOR: Moving to the patient satisfaction survey that's coming online, will we be able to break down -- will that, do you think, reflect such issues as drive time, so that we'll have yet a finer, more granular cut in terms of access?

MS. RAY: I'm sorry, excuse me?

MR. FEEZOR: We have a patient satisfaction survey that's coming online, right? I was just trying to find out if that would hit such things as differences between say small facilities versus large facilities, drive times, and things like that. Do you know?

MS. RAY: I'm going to have to check with AHRQ and CMS to see exactly what measures they're including.

MR. FEEZOR: Do you know whether any of the licensure requirements which of course is largely state as well, whether they have any required backup capacity so that if in case of disasters or major dislocations? I'd love to hear that. That's something we've seen some experience in that probably needs to be looked at, not so much from this body but the industry at large.

MS. DePARLE: At our December meeting, we talked some about using the CMS market basket versus the one that we had been using for some time. And it sounds like you're inclined to move towards the CMS one. But in the discussion of the chapter you raised two issues about it, that CMS does not indicate how frequently the base weights will be updated, and that CMS does not specifically address whether it used audited cost report data. Have we asked them? Those seem like pretty simple yes or no questions to figure out.

MS. RAY: We're in the process of talking.

MS. DePARLE: Does that mean that this might change between what we vote on today and when -- it seems like they could answer this pretty quickly. And if they did, then might we not just say okay, we're going to use CMS's market basket?

DR. MILLER: Nancy Ann, CMS is thinking about these issues. We have not gotten an answer yet.

MS. DePARLE: But we have asked them?

DR. MILLER: We have asked them and I would not anticipate getting answers between now and when we have to go to print.

MS. DePARLE: These questions seem like simple ones and it always used to annoy me when people wouldn't just ask. Did you use audited cost report data or did you not?

DR. MILLER: I can assure you we're not just sitting in our offices. We have definitely asked this question and I think CMS is thinking about what went on and what they would do to address these issues.

MS. DePARLE: Just one more thing. I haven't gotten to make this point yet this morning. Is this 2001 data we're basing this off of, am I right?

MS. RAY: The cost report? Yes.

MS. DePARLE: So we're making a recommendation for 2005 and, I know you agree with this but...

MS. RAY: The 2002 cost report file had about 40 percent of all the facilities. It was just way underreported compared to previous years.

MS. DePARLE: Let's break that down. That's because they don't turn them in on time?

MS. RAY: I don't exactly know the reasons for that. It could be the facilities. It could be the FIs. It could be CMS. There are a number of steps here that are involved.

MS. Departe: It seems to me that everyone, all of those people, have an interest in having accurate data. I know we do. So I don't know if there's some way to reflect that in our recommendations but there aren't many businesses where I think you'd be making recommendations about what to pay for a year from now based on data from four years ago. Thanks.

MS. BURKE: If I could just add, Nancy and

Nancy Ann, the same thing struck me when I read in the text that only 41 percent of the '02 cost reports were available. And I think, in fact — that's simply stated as a fact in the text. I would, in fact, say something further about that, that our preference would be certainly to have been, but unfortunately for a variety of reasons — something to highlight the fact that we're basing it on '01 because we didn't have '02, or we only had 40 percent of '02 is just outrageous. I think we ought to make note of that fact. It's not that that would be our preference by any stretch.

DR. ROWE: On page 13, you do include the returns on -- the term you use is return on equity. There's return on capital, return on economic capital, different kinds of ways to look at this. But return on equity, the range is 11 to 65 percent, which is a modestly broad range so it's hard to know how to interpret that.

But you do also indicate that three-quarters of the patients are on Medicare and that they account for about 57 percent of the revenues. So pushing some numbers around here a little bit, it does look as if they're making from the commercial payers, whoever they may be, significantly more if the costs of all patients are the same. But since that's only one-quarter of the patients when you add it all up, I still only get to returns that are less than 5 percent, in the 3 percent range pre-tax. So it still is modest.

Although as I say, it seems inconsistent with the stock prices going up and the access increasing and everything else. So it just doesn't seem to meet what most investors would see as attractive. So I think it's worth pushing this around, talking with some analysts who are in this space and getting a sense of it so we can connect the dots.

MR. SMITH: But, Jack, as you push the numbers around, I the problem is you're still assuming that the return on capital is the weighted average of the margins from different payers. It's not true. The return on capital is the pre-tax profit of the operation over the equity invested by investors.

DR. ROWE: I'm accepting the return on capital on page 13.

MR. SMITH: I understand but the return on capital and the weighted average of the margins by payers will not be equal. These folks are in the real estate business, among other things.

DR. ROWE: I understand.

MR. SMITH: So trying to figure out why they aren't the same thing, I don't think, is a very useful exercise.

DR. ROWE: I'm not trying to equate them. I see them as related not necessarily orthogonal but two separate ways to look at the valuation and I'm just trying to understand with the numbers we're given why -- it just looks to me like maybe they're making a lot more on Medicare than we're calculating is the point here. That's my point because if they weren't why are they doing so well.

MR. SMITH: That's a possible inference, for sure.

DR. ROWE: We just need to go through the whole thing again and make sure we got this right.

MR. HACKBARTH: We need to move on to the second recommendation. Nancy, do you want to do that piece of the presentation?

MS. RAY: Recall that the Commission expressed an urgent need to improve quality in our June 2000 report and endorsed the use of linking payments to quality. Medicare does not have a mechanism to directly reward facilities and physicians treating dialysis patients for improving care and making investments in improving care. Although adequacy in anemia status has improved, other measures have not. And, as pointed out in your mailing materials, mortality and rates of hospitalization remain high with very little change over the past decade.

We looked at the feasibility of implementing quality incentives for outpatient dialysis services. And here we conclude that it does appear to be feasible. Again, I just want to make it very clear by the dialysis sector we mean both dialysis facilities and physicians treating dialysis patients. The actions of both facilities and physicians affect patients' quality of care.

So we looked at four aspects to assess the

feasibility of implementing incentives. We do have measures are available that are evidence-based, developed by third parties, and agreed upon by the majority of providers. CMS can collect provider-specific information without excessive burden on providers. Data on adequacy and anemia are collected on claims. And there is an ongoing effort to collect clinical data by linking facilities with the ESRD networks and CMS.

Data are available to case-mix measures so that providers and not discouraged from taking riskier or more complex patients. As set forth in your mailing brief, providers are required to report clinical information about each patient when they are incident. There are some 17 comorbidities, patient weight, ability to ambulate and transfer. Of course, this information can always be augmented by Part A and Part B payment claims.

Finally, history has shown that providers can improve upon some aspects of quality, at least on adequacy and anemia status.

Your mailing materials include some key implication issues that the Secretary will need to think about when implementing incentives.

We were guided by two principles when thinking about these implementation issues. First, that the incentives, there their improvements on quality should reach as many patients as possible. And two, that their adverse consequences, such as cherry-picking, should be minimized.

So some of the key implementation issues include how should quality be measured. Here we've discussed basing it on a combination of both quality improvement and meeting national averages or targets. By using both methods, providers at both ends of the quality spectrum will be able to be rewarded. In this way we will be reaching a large share of providers. Consequently, the quality improvement effects of incentives will touch upon as many patients as possible.

Second, how would you pay? In here, we discuss basing this on a small share, say 1 percent of total payments. This would discouraged providers from de-emphasizing other quality improvement efforts and it

would minimize the adverse effect on providers who do not meet the quality criteria.

We spent a fair amount of time discussing which quality measures used. Here we think that aspects of dialysis adequacy, anemia, nutrition, vascular access and bone disease can all be linked to payment.

Finally, your mailing materials include other implementations the Secretary will need to consider, including collaborating with patients and provider groups, keeping the measures current over time, developing uniform ways to measure the indicators, and to verify the data collected.

Finally, it's worth noting that this will increase the administrative responsibilities for both CMS and its contractors.

So this led us to our second recommendation, that Congress should establish a quality incentive payment policy for outpatient dialysis services. This has no spending implications relative to current law.

MS. ROSENBLATT: I'm going to make this point when we talk about M+C as well, and I think I made this point at our last meeting. I think doing quality incentives is great. My concern is in the context of the Medicare system and the way it's funded, what does it mean to set aside a pool of money for this?

Because if we were doing it in the private sector, as many do, in an HMO, a lot of capitated payments end up with a withhold. And that withhold money is actually set aside, a liability is established on the balance sheet. You can point to it. There's sort of real money being put aside.

My concern in this context is just what does this mean in the program? Or would all the providers see this as just a way of cutting back 1 percent and the pool of money does not exist. That's my concern.

MR. HACKBARTH: Let me make sure I understand. So your concern is that the money "will be withheld" but not necessarily paid out and unless you can see it --

MS. ROSENBLATT: It will be withheld but it's not set aside anywhere so it will be spent elsewhere. There's no liability set up for it.

DR. MILLER: Again, what we're articulating here are a set of principles, so there's probably

different mechanisms that could be thought through, but the cleanest way to do this would be if you decided it was 1 percent, you would pay 99 cents on a claim, have the indication of how much you've paid out. And at the end of the year, based on whatever your measures, cut a second set of checks. I think that's a way it could be accomplished.

MR. HACKBARTH: Are you concerned, Alice, that the thresholds for improvement will be set so high that nobody will attain them and so there won't be any payout of quality incentives?

MS. ROSENBLATT: That's part of it. What then, if no providers qualify for it and you've ended up decreasing payments by 1 percent?

DR. MILLER: One of the things that we're trying to be clear about in setting up -- well, the slide on the principles. There's a couple of things here.

We said and articulated all through the last meeting and this meeting, we're going to try to be very clear on this, and this will be true on M+C, too. So just to get out ahead of it.

It should be both attainment and improvement. So that a person at a lower end of the distribution, if they move a certain -- and there's lots of ways to do this, percentages, points, whatever is -- they get something.

The second way that you assure that the money travels out is you try and determine, either looking at the measures or the percentages -- and the way Nancy was speaking to this is that the most patients are reached by this.

Certainly initially you would want this to travel back to -- I don't know what the exact percentage is, but a relatively large percentage of agencies. And you can do that by setting the standards in a way that you're moving up the tail of the distribution.

Another point is that Nancy has said very clearly that what we want to do with this is bring in new measures over time. So where everybody is, one concern you might have is everybody's already at this particular measure. But she's been talking about -- and this is where I'm going to lose it here really quickly -

- but nutrition and vascular access. Those are new measures and this is the way you keep quality improvement moving is moving up on existing measures and bringing new measures in. And arguably facilities should be able to play on all of that, those dimensions. I think that's the thought.

MR. HACKBARTH: There are many specific decisions that need to be made to operationalize this concept of an incentive payment. And we're not CMS. We're not an operating agency. We're not really in a position to dot all of the I's and cross all the T's. I think we would be going beyond our expertise if we try to define it down to every last detail.

Conceptually, it is not our intent to withhold money and then not pay it out. Our goal, the objective here is to provide a reward for improving quality. I think it's entirely appropriate for us in the text to emphasize that we want the money paid out to reward improvement. It's not about trying to find another way to take money out of the system.

But I don't want to go so far as to define formulas on exactly how it's going to be paid out. I think that would be inappropriate for us to do.

MS. ROSENBLATT: Can I just push it a little bit more and ask the question is it feasible for these payments to be made? These types of payments are made by Medicare intermediates. I don't see Medicare intermediaries being able to do this. I think CMS itself would need to do this, I don't know, maybe issue memos to -- it just seems to me the implementation of this is pretty difficult.

I know we can't think through all the details, but I'm just trying to get us to think through at sort of the first cut, are we recommending something that can really happen?

MS. RAY: I would just like to put on the table that CMS is already proposing to link payment to quality in the new ESRD disease management demo. So I think the agency has already thought through some of these issues. Again, in the new demo, they will again be paying both on the basis of improvement and attainment.

DR. NEWHOUSE: I thought the analogy to what

Alice was raising first was was this object neutral ex ante or ex post? So the analogy would be to the hospital outlier system where the threshold is set ex ante, 5 percent is knocked off the base rate, and then however much money is paid out is paid out. And it may or may not be 5 percent at the end of the day versus some system that, in fact, guaranteed that 100 percent would be paid out at the end of the day.

I don't have a strong view about whether we should comment on whether this is budget neutral ex ante or ex post, but I think there is still an issue there.

DR. ROWE: Nancy is probably expecting this comment, but I think there are two things about this that are really interesting and important. One is that it begins to migrate from a dialysis program to an endstage renal disease program, which is what it's supposed to be, because we're picking up nutrition and -- although that albumin level is a measure of adequacy of management of dialysis patients, it's managed by physicians in many ways. And picking up bone disease and prescriptions for bisphosphonates and vitamin D and calcium monitoring, et cetera, is done by physicians, et cetera, not a dialysis facility, per se.

Although, if you put money in for quality it will give the dialysis facilities incentives to hire nutritionists to spend more time with the patients while they're on the machines making sure their diet is appropriate, et cetera, because the patients are captive there while they're being dialyzed. So I'm interested in that.

I think we should emphasize somewhere in the chapter the business about transitioning from a dialysis program to an end-stage renal disease program and point to the disease management demonstration as another important step there, Nancy.

The second thing I would say, though, is on page 29 you -- I won't use the word admit, that's not quite fair -- but you indicate that many of these outcomes are influenced or can be influenced by both the doctors and the dialysis facility. But it's not clear to me after that that any of this quality money is going to the doctors. It sounds like it's all going to the dialysis facility.

And I've got to tell you, it's really all about the doctor. I mean, it is really all about having physicians who are understanding that these are very important things and that there are new developments all the time, and they're in touch with the patient. They're getting a capitation fee on a monthly basis already. They've been doing that for years. There's no reason why, vis-a-vis what Alice says, there can't be some additional quality payments in the capitation.

MS. RAY: We will work on the text to make sure it is crystal clear that we are referring to both dialysis facility and the doctors receiving a monthly capitated payment.

MR. HACKBARTH: Should we include that in the bold-faced recommendation?

MS. RAY: We can definitely --

MR. HACKBARTH: I think we ought to include it actually in the language of the bold-faced recommendation, that this applies to both the facility and the physician.

DR. ROWE: You say it on 29 but then you talk about providers. And to be fair, in the context of every other document we've ever seen in this, provider means dialysis facility.

MS. RAY: You're right.

DR. ROWE: So if I were representing the nephrologists, I'd say let's be explicit.

MS. DePARLE: Jack made one of my points, which was about the doctor. I guess in response to Alice's point, and Nancy made this argument herself, I think it is possible to do this. I don't think it's easy to do it, especially when you also involve the doctor. But I said last time and I'll say this time, that I'm a little concerned about doing it on a budget neutral basis given some of the data that -- now I've been sitting here searching for it, Nancy, but I know it's in here, about the GAO report recently about some of the deficiencies in centers and CMS's neglect in oversight.

MS. RAY: Right. I had mentioned that at the December meeting. GAO issued a report, I think it was in December, that specifically looked at CMS's and state's -- their survey and certification efforts, how

well they're inspecting facilities. They found deficiencies in that. However -- and, of course, they suggested that CMS and the states improve upon these quality assurance efforts.

he report also does make note that there has been some improvement since GAO's report prior to this one. So I think that's important to note, too.

And I also think the quality assurance reflects Medicare ensuring minimal standards of care, whereas the incentives as we've laid them out address trying to improve quality of care. Both are important aspects, clearly. And I think there are ways to improve the quality assurance system, for example, having CMS use intermediate sanctions and posting the data on the compare website. MedPAC made recommendations on that. And I think the incentives target a different angle of quality, trying to improve the level and narrow the gap.

MS. DePARLE: I guess I was just surprised, maybe I shouldn't have been. But I was surprised at the level of deficiencies among some of the -- and the percentage of centers that had them. And I don't think we know. I think what you're saying is the oversight may have improved. Frankly, that's a function of the discretionary dollars that the Agency gets for survey and cert, and they have to do annual nursing home surveys and they don't have to do annual dialysis center surveys. It's just that simple.

But given the levels of deficiencies, I just have some concern -- it's a small about, 1 percent of payments. And if we believe that payments are adequate, I suppose it's not that much. But I have a concern about that.

MS. RAPHAEL: I remember in the text that you sent us, Nancy, one thing that surprised me was that margins and cost had no correlation with outcomes. In fact, I think you indicated that the higher the margins, the poorer the outcomes. I'm not sure I got that correct, but could you just explain that because I think it pertains to this issue.

MS. RAY: That was our analysis that we published in our June 2003 report where we looked at outcomes and providers' costs. And there we did not find, with composite rate costs, we found little

association between higher costs and outcomes. We found no significant association there.

DR. MILLER: So a facility might argue that they have higher costs but then you're getting higher quality. And that's why we went through this exercise and we can't establish that relationship. That's part of what makes us a little more comfortable with...

MR. HACKBARTH: Why don't you put the first recommendation up? All opposed to the draft recommendation? All in favor? Abstain?

Recommendation two. This will be amended as we discussed to make specific reference to physicians. All opposed? All in favor? Abstain?

Okay, thank you. Next up is Medicare+Choice.

MS. BURKE: Glen, just while people are coming up. In the second recommendation the suggestion was there was no cost implication. I thought I saw a reference in the text that discussed that it might well have some additional administrative costs. I'm not sure that no is a fair representation.

MR. HACKBARTH: Sheila's making the point that there will be an administrative cost attendant to implementing the quality incentives.

MS. BURKE: Potentially.

MR. HACKBARTH: But we say it has no budgetary effect.

DR. MILLER: Your point is well taken. A lot of what we're doing when we do this -- and this is more technical than we need to get into -- we're looking at benefit baselines. But you're right, conceptually there is an administrative cost.

 $\ensuremath{\mathsf{MS}}.$  BURKE: And we ought to at least acknowledge that.

DR. MILLER: I completely agree.